

Amendments to the Claims:

1. – 20. (canceled)

21. (currently amended) An in-process control A method in a production run of an on-going packaging process for pharmaceutical formulations to test of checking the
leaktightness of a sealed container that which holds a pharmaceutical active
substance formulation in a chamber provided inside said container, the sealed
container also holding a gas (the second gas), the method comprising the steps of a)
acting upon the sealed container with a first gas which differs from the second gas
enclosed within the container such that any the increase in the quantity of the first
gas inside the chamber can be analyzed; analysed and b) opening the container
and removing a sample from some of the gas which is located inside the chamber;
and c) analyzing the sample for the presence of the gas for the active substance
formulation, for the purpose of qualitative, quantitative or both analysis, wherein both
the acting and opening is carried out at a temperature of 0°C to 50°C.

22. (currently amended) The method according to claim 21, wherein characterised
in that the sealed container is a sealed foil container comprising which consists of at
least one or more covering film layers and one or more base film layers which may in
turn consist of one or more layers, the covering film and the base film being firmly
joined together along their periphery.

23. (currently amended) The method according to claim 22, wherein characterised
in that the sealed foil container is a blister.

24. (currently amended) The method according to claim 23, wherein the one or more covering film layers and the one or more base film layers are characterised in that the foil material for each of the films is selected, independently of one another, from the group consisting of: comprising metal foils, plastic films, or composite films, and/or it is a layer of paper.

25. (currently amended) The method according to claim 24, wherein characterised in that at least one of one or more covering film layers or the one or more base film layers the films is an aluminum aluminium foil.

26. (currently amended) The method according to claim 24, wherein at least one of one or more covering film layers or the one or more base film layers is characterised in that at least one of the films consists of a material selected from the group consisting of: comprising polyvinyl chloride, cycloolefin copolymer, polychlorotrifluoroethylene, polyethylene, polypropylene, polyethylene terephthalate, polycarbonates, polyesters, polyacrylates, and and/or polyamides.

27. (currently amended) The method according to claim 21, wherein characterised in that the sealed container is a sealed, two-layer, bottle-like container with a rigid outer shell and an inner container mechanically attached to the outer shell only at certain points and able to collapse in on itself relative to the outer container.

28. (currently amended) The method according to claim 27, wherein characterised in that the sealed, two-layer, bottle-like container has been produced by a coextrusion process.

29. (currently amended) The method according to claim 27, wherein characterised in that the rigid outer shell container consists of polypropylene, and the inner container consists of polyethylene.

30. (currently amended) The method according to claim 21, wherein characterised in that the sealed container is a sealed, collapsible bag provided with a flange.

31. (currently amended) The method according to claim 30, wherein characterised in that the sealed, collapsible bag comprises consists of a metal foil, such as, for example, an aluminium foil a plastic film, or both, or a plastic-coated metal foil.

32. (currently amended) The method according to claim 30, wherein characterised in that the sealed, collapsible bag is embedded in a metal sleeve.

33. (currently amended) The method according to claim 21, wherein the step of acting upon the sealed container with the gas characterised in that the action is carried out at a pressure difference between the chamber interior of the container and the gas its outer environment of 0.1 to 10 bar.

34. (previously presented) The method according to claim 33, wherein the pressure difference is between 0.5 to 5 bar.

35. (previously presented) The method according to claim 34, wherein the pressure difference is between 1 and 2 bar.

36. (currently amended) The method according to claim 21, wherein the gas is acted upon the sealed container characterised in that the action is carried out by using permeation effects at a pressure difference of about zero between the chamber interior of the container and the gas by permeation effects, diffusion, or permeation effects and diffusion outer environment or diffusion or both with little or no pressure difference between the interior and exterior of the container.

37. (currently amended) The method according to claim 21, wherein characterised in that the gas used for the action is selected from the group consisting of: comprising hydrogen, water vapor vapour, noble gases such as helium, neon, argon, krypton, carbon dioxide, nitrogen, carbon monoxide, carbon-sulfur sulphur gases, sulfur sulphur dioxide, hydrogen sulfur sulphide, hydrocarbons such as methane or ethane, fluorohydrocarbons such as TG 134a or TG 227, or chlorofluorohydrocarbons.

38. (currently amended) The method according to claim 37, wherein characterised in that the gas used for the action is helium.

39. (currently amended) The method according to claim 21, wherein characterised in that the steps of opening the sealed container and removal of the gas sample are carried out in a single step.

40. (new) The method according to claim 21, carried out at a temperature of 0°C to 50°C.